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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,562	09/16/2003	Nina Rautonen	17031	2985

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SCULLY SCOTT MURPHY & PRESSER, PC
400 GARDEN CITY PLAZA
SUITE 300
GARDEN CITY, NY 11530

EXAMINER	
BLAND, LAYLA D	

ART UNIT	PAPER NUMBER
1623	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/663,562	RAUTONEN ET AL.	
	Examiner	Art Unit	
	LAYLA BLAND	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 June 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5-13,16-19,24,26-28,30,32-35,38 and 40-54* is/are pending in the application.

4a) Of the above claim(s) *52-54* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5-13,16-19,24,26-28,30,32-35,38 and 40-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to Applicant's amendment submitted June 23, 2010. Claims 1, 16, 38, 41, and 45 are amended and claims 2-4, 14-15, 20-23, 25, 29, 31, 36, 37, and 39 are canceled. Claims 1, 5-13, 16-19, 24, 26-28, 30, 32-35, 38, and 40-54 are pending. Claims 52-54 are withdrawn from consideration as being directed to a non-elected invention

Claims 1, 5-13, 16-19, 24, 26-28, 30, 32-35, 38, and 40-51 are examined on the merits herein.

In view of Applicant's amendment submitted June 23, 2010, the rejection of claims 1, 5-13, 16-20, 24, 26-28, 30, 32-35, 37, and 42-46 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn. The claims have been amended to correct dependency and to clarify the patient populations and disorders being treated.

In view of Applicant's amendment submitted June 23, 2010, the rejection of claims 1, 5-13, 16-20, 27, 28, 30, 32-35, 38, 42 under 35 U.S.C. 102(b) as being anticipated by Livesey et al. is withdrawn. The rejection was directed to treatment of an aged mammal, which is no longer recited in the claims.

The following rejections of record are maintained:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

> the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 5-13, 16-19, 24, 27, 28, 32-35, 38, 40-44, and 47-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stahl et al. (CA 2340103A1, February 2, 2000, of record) in view of Jie (Am J Clin Nutr 2000; 72:1503-9, PTO-1449 submitted November 17, 2003), Brokx et al. (WO 02/39832, May 23, 2002, of record), Livesey et al. (European Journal of Clinical Nutrition (1993) 47, 419-430, of record) and Beyer (Medical nutrition therapy for lower gastrointestinal tract disorders, in Mahan LK, Escott-Stump S (eds): Krause's Food, Nutrition and Diet Therapy (ed 10), Philadelphia, PA, WB Saunders, 2000, pp 667-694, of record).

Stahl teaches dietetic foods containing of a mixture of carbohydrates, which remain undigested in the gastrointestinal tract and reach the large intestine without being resorbed, wherein the carbohydrates have prebiotic action [see abstract]. The carbohydrate mixture contains at least compounds A and B, which remain undigested in the gastrointestinal tract and reach the large intestine unresorbed, wherein A is a

monosaccharide or oligosaccharide and B is a polysaccharide [pages 3-4]. A prebiotically active carbohydrate reaches the large intestine undigested and encourages the growth and/or activity of bacterial species in the intestine, and consequently promotes health [page 6, lines 1-6, and claim 12]. Preferably, the carbohydrates are bifidogenous and/or promote lactic acid bacteria [page 7, lines 28-30, and claim 3]. Carbohydrates A and B should be of a different size and structure [page 8, lines 27-31] so that a synergistic effect may occur [page 9, lines 9-14]. The combination of carbohydrates is more efficient than only one carbohydrate [page 7, lines 17-26]. The carbohydrate mixtures are effective for stabilization of natural microflora, prevention of pathogenous substances/organisms, and acceleration of wound healing [page 8, lines 13-20], and treatment of symptoms/diseases occurring in conjunction with disturbed intestinal flora [page 8, lines 22-25]. Normal intestinal flora might not be present in babies or in subjects who have taken antibiotics [page 2, lines 15-19]. Compositions include baby formula, human milk fortifier, pharmaceuticals, and dietetic supplements [page 13, lines 1-6, and claim 12].

Stahl's teaching of suitable carbohydrates is broad and Stahl does not expressly teach polydextrose and lactitol as the two carbohydrates.

Jie teaches that polydextrose is not digested or absorbed in the small intestine and increases the growth of favorable microflora [page 1503, first full paragraph in second column], such as Lactobacillus and Bifidobacterium species [see abstract].

Brokx teaches that lactitol is a prebiotic which improves intestinal microflora [see abstract], particularly Lactobacilli and Bifidobacteria [page 1, lines 26-28]. As such, it

can be used to treat intestinal infections, colon cancer, diarrhea, or for enhancing immunity [claim 7].

Livesey teaches that the hydrogen breath test is used to detect the fermentation of carbohydrates that escape absorption in the small intestine, and works by measuring hydrogen produced by large-bowel-anaerobic microorganisms in the presence of fermentable carbohydrate [page 419, first paragraph]. The combination of polydextrose and lactitol doubled the breath hydrogen anticipated from their individual contributions, showing a positive interaction [see abstract].

Bayer teaches that prebiotics or fermentable sugars can be used to treat diarrhea [page 710, first paragraph in the second column], lactose intolerance [page 720, second paragraph in the second column], inflammatory bowel disease [page 724, second paragraph], and pouchitis, which is an inflammatory condition related to bacterial overgrowth [page 735, first paragraph].

It would have been obvious to one of ordinary skill in the art to administer polydextrose and lactitol to a subject in need of improved bowel health or restoration of natural microflora. Stahl teaches that mixtures of prebiotic carbohydrates are useful for improving health, stabilization of natural microflora, prevention of pathogenous substances/organisms, and acceleration of wound healing. Although Stahl does not specifically teach polydextrose and lactitol as the two carbohydrates, polydextrose and lactitol are known to cause the growth of Lactobacillus and Bifidobacterium, which is a preferred characteristic of Stahl's carbohydrates. Furthermore, the skilled artisan would choose the particular combination of polydextrose and lactitol because of the synergistic

effect taught by Livesey. Specifically, subjects with disturbed intestinal flora, babies, and subjects who have taken antibiotics can benefit from prebiotics (Stahl), and diarrhea, lactose intolerance, inflammatory bowel disease, and pouchitis can be treated using prebiotics (Bayer). Thus, it would have been obvious to administer prebiotics to any of those subjects, and particularly the prebiotic combination of polydextrose and lactitol because the combination has a synergistic effect. It would have been further obvious to use purified polydextrose to avoid ingestion of potentially harmful impurities.

Claims 1, 5-13, 16-19, 24, 27-28, 30, 32-35, 38, and 40-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stahl et al. (CA 2340103A1, February 2, 2000, of record) in view of Jie (Am J Clin Nutr 2000; 72:1503-9, PTO-1449 submitted November 17, 2003), Brokx et al. (WO 02/39832, May 23, 2002, of record), Livesey et al. (European Journal of Clinical Nutrition (1993) 47, 419-430, of record) and Borody (US 5,443,826, August 22, 1995, of record).

Stahl teaches dietetic foods containing of a mixture of carbohydrates, which remain undigested in the gastrointestinal tract and reach the large intestine without being resorbed, wherein the carbohydrates have prebiotic action [see abstract]. The carbohydrate mixture contains at least compounds A and B, which remain undigested in the gastrointestinal tract and reach the large intestine unresorbed, wherein A is a monosaccharide or oligosaccharide and B is a polysaccharide [pages 3-4]. A prebiotically active carbohydrate reaches the large intestine indigested and encourages the growth and/or activity of bacterial species in the intestine, and consequently

promotes health [page 6, lines 1-6, and claim 12]. Preferably, the carbohydrates are bifidogenous and/or promote lactic acid bacteria [page 7, lines 28-30, and claim 3]. Carbohydrates A and B should be of a different size and structure [page 8, lines 27-31] so that a synergistic effect may occur [page 9, lines 9-14]. The combination of carbohydrates is more efficient than only one carbohydrate [page 7, lines 17-26]. The carbohydrate mixtures are effective for stabilization of natural microflora, prevention of pathogenous substances/organisms, and acceleration of wound healing [page 8, lines 13-20], and treatment of symptoms/diseases occurring in conjunction with disturbed intestinal flora [page 8, lines 22-25]. Normal intestinal flora might not be present in babies or in subjects who have taken antibiotics [page 2, lines 15-19]. Compositions include baby formula, human milk fortifier, pharmaceuticals, and dietetic supplements [page 13, lines 1-6, and claim 12].

Stahl's teaching of suitable carbohydrates is broad, Stahl does not expressly teach polydextrose and lactitol, and Stahl does not teach treatment of a subject suffering from celiac disease.

Jie teaches that polydextrose is not digested or absorbed in the small intestine and leads to the growth of favorable microflora [page 1503, first full paragraph in second column], and causes Lactobacillus and Bifidobacterium species to increase [see abstract].

Brokx teaches that lactitol is a prebiotic which improves intestinal microflora [see abstract], particularly Lactobacilli and Bifidobacteria [page 1, lines 26-28]. As such, it

can be used to treat intestinal infections, colon cancer, diarrhea, or for enhancing immunity [claim 7].

Livesey teaches that the hydrogen breath test is used to detect the fermentation of carbohydrates that escape absorption in the small intestine, and works by measuring hydrogen produced by large-bowel-anaerobic microorganisms in the presence of fermentable carbohydrate [page 419, first paragraph]. The combination of polydextrose and lactitol doubled the breath hydrogen anticipated from their individual contributions, showing a positive interaction [see abstract].

Borody teaches that disorders associated with abnormal microflora or an abnormal distribution of microflora in the gastrointestinal tract can be treated by restoring normal healthy flora [see abstract]. Celiac disease, inflammatory bowel disease, antibiotic associated colitis, irritable bowel syndrome, and small bowel bacterial overgrowth are examples of such disorders [column 3, lines 25-34].

It would have been obvious to one of ordinary skill in the art to administer polydextrose and lactitol to a subject in need of improved bowel health or restoration of natural microflora. Stahl teaches that mixtures of prebiotic carbohydrates are useful for treating subjects which have disturbed intestinal flora. Although Stahl does not specifically teach polydextrose and lactitol as the two carbohydrates, polydextrose and lactitol are known to cause the growth of Lactobacillus and Bifidobacterium, which is a preferred characteristic of Stahl's carbohydrate mixture. Furthermore, the skilled artisan would choose the particular combination of polydextrose and lactitol because of the synergistic effect taught by Livesey. Specifically, subjects with disturbed intestinal flora

which may be treated by restoration of normal flora include patients having celiac disease, inflammation, and antibiotic associated colitis, as taught by Borody. Thus, it would have been obvious to administer prebiotics to any of those subjects, and particularly the prebiotic combination of polydextrose and lactitol because the combination has a synergistic effect. It would have been further obvious to use purified polydextrose to avoid ingestion of potentially harmful impurities.

Claims 26 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stahl in view of Jie, Brokx, Livesey and Beyer as applied to claims 1, 5-13, 16-19, 24, 27-28, 30, 32-35, 38, 40-44, and 47-51 above, and further in view of Borden et al. (US 5,601,863, February 11, 1997, of record).

Jie and Livesey teach the use of polydextrose, as set forth above, but do not teach the use of hydrogenated polydextrose.

Borden teaches that polydextrose and hydrogenated polydextrose are both enzyme-resistant and functional equivalents as food additives [columns 1-2 and paragraph bridging columns 6-7].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute hydrogenated polydextrose for polydextrose in the above described method. Hydrogenated polydextrose is known as a functional equivalent of polydextrose, having improved properties such as color and flavor. Thus, the skilled artisan would expect that an improvement in color and flavor using hydrogenated polydextrose.

Claims 26 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stahl in view of Jie, Brokx, Livesey and Borody as applied to claims 1, 5-13, 16-19, 24, 27-28, 30, 32-35, 38, and 40-51 above, and further in view of Borden et al. (US 5,601,863, February 11, 1997, of record).

Jie and Livesey teach the use of polydextrose, as set forth above, but do not teach the use of hydrogenated polydextrose.

Borden teaches that polydextrose and hydrogenated polydextrose are both enzyme-resistant and functional equivalents as food additives [columns 1-2 and paragraph bridging columns 6-7].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute hydrogenated polydextrose for polydextrose in the above described method. Hydrogenated polydextrose is known as a functional equivalent of polydextrose, having improved properties such as color and flavor. Thus, the skilled artisan would expect an improvement in color and flavor using hydrogenated polydextrose.

Response to Arguments

Applicant argues that Stahl teaches a mixture of carbohydrates, particularly a monosaccharide and a polysaccharide, and that lactitol is neither a carbohydrate nor a monosaccharide. This argument has been carefully considered but is not persuasive. First, Stahl's teaching of carbohydrate A is not limited to monosaccharides. The

abstract given on the third page of the Stahl reference states that component A can be a monosaccharide or an oligosaccharide, and a disaccharide is mentioned particularly. Stahl also requires that at least 80% of the carbohydrates have a prebiotic effect, which lactitol is known to have. Further, although the definition given in Exhibit A states that a carbohydrate must have a hydrogen:oxygen ratio of 2:1, the art as a whole recognizes sugar alcohols such as lactitol as carbohydrates. The prior art contains numerous references to lactitol as a carbohydrate. For example, Patil et al. (British Journal of Nutrition (1987), 57, 195-199) refers to lactitol as a disaccharide analog of lactose [see abstract]. Livesey's abstract refers to lactitol as an alternative carbohydrate. Web definitions of "carbohydrate" state that the atom ratio is "usually" in the ratio 1:2:1 [see first definition], and that sugar alcohols are carbohydrates [see second definition]. Thus, the prior art as a whole clearly recognizes lactitol as a sugar alcohol, a disaccharide, and a carbohydrate.

Applicant argues that the increased hydrogen production of polydextrose and lactitol shown by Livesey could come from harmful bacterial fermentation as any other, and Livesey doesn't suggest that disorders could be treated with the combination. This argument has been carefully considered but is not persuasive. Because polydextrose and lactitol are both known in the art as prebiotics which increase the population of healthy microflora, the skilled artisan would not expect that the hydrogen production shown by Livesey was a result of harmful bacterial fermentation. Livesey was cited to show that the art reconizes a synergistic relationship with respect to polydextrose and lactitol. Since both are known in the art as prebiotics, and prebiotics are known in the

art for treatment of certain disorders, and combinations of carbohydrates are particularly advantageous, the skilled artisan would recognize that polydextrose and lactitol would be useful for treating those disorders.

Applicant argues that Beyer teaches away from the claimed invention because neither lactitol nor polydextrose are fermentable sugars, and sugar alcohols can worsen osmotic diarrhea. This argument is not persuasive because Jie teaches that polydextrose is partially fermented, which leads to the growth of favorable microflora. Contrary to Applicant's argument, lactitol is a fermentable sugar. See Gee et al. (Br. J. Nutr., 1996 May; 75(5):757-76, abstract only), which states "We studied the effects of a fermentable sugar-alcohol (lactitol). Furthermore, although Brokx does not expressly refer to fermentation, Brokx teaches that lactitol improves intestinal microflora, which is a consequence of fermentation, as taught by Jie.

Applicant argues that Borody is drawn to restoring microflora by the use of live bacteria, which is different from polydextrose and polyol which are free from live bacteria. Indeed, this is so. However, Borody teaches that problems caused by abnormal microflora in the gastrointestinal tract can be corrected by restoring normal healthy flora. Although Borody teaches a different method to achieve this, the cited references teach that prebiotics such as polydextrose and lactitol can be used to promote healthy flora and are indicated for treatment of symptoms or diseases associated with disturbed intestinal flora. Thus, the art teaches a known method (administration of prebiotics) for solving a known problem (disturbed intestinal flora and

associated disorders), by a known means (fermentation of carbohydrates to restore healthy flora).

For these reasons, the rejections are maintained.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAYLA BLAND whose telephone number is (571)272-9572. The examiner can normally be reached on Monday - Friday, 7:00 - 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anna Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Layla Bland/
Examiner, Art Unit 1623

/Shaojia Anna Jiang/
Supervisory Patent Examiner
Art Unit 1623